NOT FOR PUBLICATION **CASE CLOSED**

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WILLIAM M. NEMCIK,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 05-1469 (JAP)
	:	
UNITED STATES OF AMERICA	:	**OPINION**
	:	
Defendant.	:	
	:	

PISANO, District Judge.

This matter comes before the Court upon a Complaint brought by Plaintiff, William Nemcik ("Plaintiff") against Defendant, United States of America ("Government" or "Defendant"). Plaintiff alleges that the Government, by and through its duly authorized agents, servants and/or employees, were negligent in their treatment of Plaintiff, which constituted medical malpractice.

From April 1, 2008 to April 7, 2008, the Court conducted a non-jury trial. After careful consideration of the extensive record before it, the Court sets forth herein its findings of facts and conclusions of law pursuant to Fed. R. Civ. P. 52(a), and finds in favor of the Government.

I. Background

A. Procedural History

This case concerns whether the medical treatment Plaintiff received on March 21, 2002 was negligent and constituted medical malpractice. Plaintiff underwent extensive lumbar spine surgery at the VA Hospital. While in recovery, Plaintiff discovered he could not see out of his right eye and his vision was blurry in his left eye. As a result of a medical condition known as posterior ischemic optic neuropathy ("PION")[1], Plaintiff has permanently impaired eye sight.

Based on Plaintiff's resulting impairment, on February 6, 2004, Plaintiff submitted an administrative claim, which the Government formally denied by letter dated October 14, 2004. On March 16, 2005, pursuant to the Federal Tort Claims Act, 28 U.S.C. § 1346(b), Plaintiff filed a Complaint against the Department of Veteran Affairs, d/b/a/ The Harbor Healthcare System ("VA Hospital"), arising from the medical care Plaintiff received while a patient at the VA Hospital. In Count One of his Complaint, Plaintiff alleged that "the medical care provided to the Plaintiff at the [VA Hospital] and by the [VA Hospital's] agents, representatives and/or employees, beginning in March 2002 and continuing through April 23, 2002, fell outside the standards of good and accepted medical practice, was negligent, and was careless and reckless." Compl., ¶ 7. Plaintiff further asserted that the VA Hospital was "guilty of negligence and malpractice" for:

> a) employing physicians, surgeons, internists, orthopedists, anesthesiologists, radiologists, residents, pharmacists, nurses, technicians and other personnel who are unskilled, unfit and incompetent for such employment and permitting them to attend, advise, diagnose, treat and care for Plaintiff;
>
> b) failing and neglecting to provide and furnish Plaintiff with the proper and

[1] A diagnosis of PION means that the amount of oxygen delivered to the posterior optic nerve, which begins after the optic nerve exits the globe of the eyeball and continues until it enters the brain, was insufficent. Restricted blood flow can lead to permanent damage to the optic nerve resulting in blindness.

necessary care and treatment for which he had contracted;

c) failing and neglecting to employ physicians, surgeons, internists, orthopedists, anesthesiologists, radiologists, residents, pharmacists, nurses, technicians and other personnel who possessed that skill and learning ordinarily possessed by such individuals;

d) failing to recognize and protect against the risks of sight loss during the management of extended spinal surgery;

e) failing to appropriately respond to surgical conditions present that created an undue risk of harm to Plaintiff's eye sight;

f) failing and neglecting to draft, promulgate, adopt and/or enforce appropriate rules, regulations, policies, procedures, by-laws, orders and similar provisions could have and would have prevented the acts of malpractice and negligence committed against Plaintiff and which could have and should have prevented the injuries that he sustained including permanent and severe impairment of his vision;

g) all other acts of malpractice to be determined throughout the course of discovery.

Compl., ¶ 8. The Complaint sought an unspecified amount in damages for the "pain, suffering and economic injuries sustained by [Plaintiff] as a result of the negligence of the [VA Hospital] through its agents, representatives and/or employees." Compl., ¶ 10.

On October 21, 2005, the parties stipulated to the dismissal of the VA Hospital and substituted the United States of America as the sole Defendant. Additionally, during the course of the action, Plaintiff offered another theory of liability based upon the duty of informed consent, which the Government denied.

Prior to the start of the bench trial, on March 26, 2008, the Government filed motions *in limine* to preclude Dr. Elizabeth Frost from testifying as an expert witness on the grounds that she was unqualified to render an opinion, her testimony on causation was unreliable and failed to

meet the standards of Fed. R. Evid. 702 and factors set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and her opinion did not fit with the facts of the case. The Government also sought to preclude Dr. Floyd Warren from testifying as to causation since Plaintiff did not designate Dr. Warren as an expert witness. Lastly, the Government asked the Court to preclude Plaintiff from offering evidence that Dr. Frost was not invited to be a consultant on the American Society of Anesthesiologists ("ASA") Task Force because the issue was entirely irrelevant to Plaintiff's claims of negligence. The Court determined that Dr. Frost met the *Daubert* standards and allowed her testimony. Because Plaintiff's counsel stipulated that he did not intend to question Dr. Warren about causation, the Court also allowed his testimony. The Court, however, did not allow Plaintiff to offer evidence that Dr. Frost was not invited to the ASA Task Force as the evidence was immaterial.

During a five-day bench trial, which began on April 1, 2008, the Court provided both parties with opportunity to present evidence. During Plaintiff's case-in-chief, Plaintiff offered Dr. Frost as an anesthesiology expert witness. Additionally, for fact witnesses, Plaintiff proffered his own testimony as well as Dr. Warren, Stephanie Reimers, and Richard Reimers. The Government, during its case-in-chief, offered Dr. Steven Roth as its neuro-anesthesiologist expert witness and Dr. Larry Frohman as its expert neuro-opthalmologist. The Government also proffered several fact witnesses including Dr. John Houten, Dr. Jan Purgess, and Dr. Kenneth Grush.

After the close of the case, both parties submitted their proposed findings of fact as well as a stipulation of facts. The Court now renders its decision.

II. Findings of Fact

Plaintiff entered the VA Hospital on March 20, 2002, for extensive lumbar spine surgery to include multilevel lumbar fusion with instrumentation (fixation of the vertebrae with metal screws) and the harvesting of bone grafts from his hip. The surgery was scheduled for March 21, 2002. Plaintiff's diagnosis at the time of his admission was spinal stenosis, which is a narrowing of the vertebral canals and compression of nerves that service the lower extremities.

On admission, Plaintiff was at the age of sixty-four, weighed 262 pounds, with a height of approximately six feet, four inches, and was taking medicine for hypertension and high cholesterol. At the time of Plaintiff's admissions, he was retired from his occupation as a foreign car salesman and was receiving military pension for hearing loss and a hand injury. The March 21, 2002 surgery was the fourth spinal surgery Plaintiff had undergone; Plaintiff had two prior lumbar spine surgeries in 1977 and 1998, and a cervical spine fusion in 1998.

Plaintiff's neurosurgery team consisted of Dr. John Ratliffe, attending neurosurgeon; Dr. John Houten, chief neurosurgery resident; and Dr. Takamichi Yamamoto, neurosurgery resident. During the majority of the operation, Dr. Kenneth Grush, the attending anesthesiologist, and Mary Murphy, a certified nurse anesthetist, provided Plaintiff with the anesthesiology services. Dr. Jan Purgess came into the operating room toward the end of the surgery to relieve Dr. Grush. Dr. Purgess was also the attending anesthesiologist who conducted the consultative, pre-operative evaluation and examination of Plaintiff on February 25, 2002.

On March 21, 2002, the day of Plaintiff's surgery, anesthesia was administered to Plaintiff at approximately 8:10 am. The surgeons commenced the operation at about 9:30-9:35

a.m. Jt. Ex. at 291. Surgery concluded at approximately 6:30 p.m., and Plaintiff was taken to the Surgical Intensive Care Unit ("SICU") to recover, where Plaintiff remained until the next morning. Extubation of Plaintiff occurred around 7:15 a.m. on March 22, 2002. Around 9:00 a.m., Plaintiff complained that he could not see out of his right eye and that he had blurry vision in his left eye. An ophthalmology consult was called and Dr. Richard Levy, an ophthalmology resident, examined Plaintiff in conjunction with Dr. Warren, the attending neuro-ophthalmologist. The examination revealed that Plaintiff had no light perception in his right eye and the vision in his left eye, at that time, had an equivalent of 20/70 acuity with visual field impairment. The doctors diagnosed Plaintiff with PION.

Plaintiff has permanently impaired eye sight. He has no light perception in his right eye and although his left eye is capable of normal acuity, he has a visual field impairment. Plaintiff does not see the lower half of the visual field in his left eye; in other words, he cannot see below the mid-line.

A. Pre-Operative Evaluation

Doctors in the VA Neurosurgery outpatient clinic in New York saw Plaintiff three times between November 2001 and January 2002 for his back problems. Jt. Ex. 2 at 250-52. Plaintiff testified that, at that point in time, he was in a lot of pain and it was becoming more difficult to walk and stand. T. Nemcik 182:22-183:4. Because conservative therapies no longer seemed to be effective, the doctors recommended a multi-level lumbar laminectomy with bone graft and fusion to alleviate Plaintiff's back pain. Jt. Ex. at 250-52.

On February 21, 2002, doctors from the VA Internal Medicine Service performed their

pre-operative evaluation of Plaintiff. They took Plaintiff's vital signs and physically examined Plaintiff. The doctors noted that Plaintiff had no known allergies, was a smoker, and took medication for hypertension and niacin for high cholesterol. Jt. Ex. 2 at 254. The doctors also took a chest x-ray and echocardiogram ("EKG") of Plaintiff. Based on Plaintiff's lab results, Plaintiff's hemoglobin level was normal at 15.8 and his hematocrit was 45.8. Jt. Ex. 2 at 258. The EKG was also normal and the doctors also prescribed a low dose of atenolol to decrease any potential cardiac complications during the surgery. Jt. Ex. 2 at 256; T. Purgess 626:18-627:7. Lastly, the doctors noted that general anesthesia would be administered. Jt. Ex. 2 at 254.

On February 25, 2002, Dr. Purgess conducted a pre-operative anesthetic consultation of Plaintiff to assess whether Plaintiff was in optimal condition for his age and in light of his medical problems. Jt. Ex. 2 at 259; T. Purgess 627:14-18. Although Dr. Purgess performed the pre-operative consult, he had not been assigned to attend Plaintiff's surgery; therefore, he was examining Plaintiff in a consultative capacity rather than as a treating physician. T. Purgess 330:1-9. During the consultation, Dr. Purgess reviewed Plaintiff's medical history and identified any major problems that could impact the anesthetic such as Plaintiff's pre-operative consult evaluation, lab results, and chest x-ray report. T. Purgess 622:22-623:7; T. Roth 339:3-10. Dr. Purgess also conducted a physical examination of Plaintiff to determine whether Plaintiff's mouth, neck, and lungs would accept intubation. T. Purgess 627:19-628:7.

As he did not have specific recollection of his pre-operative anesthetic consultation with Plaintiff, Dr. Purgess testified that, as part of his routine, he would have told Plaintiff what the anesthesiologist would be doing during his surgery, which included inducing a state of anesthesia intravenously, placing monitors, and an arterial line, intubating Plaintiff to help maintain his

breathing, and alerting Plaintiff that the removal of the tube would depend on whether he was strong enough. T. Purgess 630:21-631:6. Further, before asking Plaintiff if he had any questions, Dr. Purgess noted that he would have told Plaintiff of other possible problems that could arise such as nausea or vomiting and that other serious complications could occur. T. Purgess 631:7-14. Dr. Purgess did not present Plaintiff with any consent form because VA protocol requires the surgeon to give the patient the consent forms for surgery, anesthesia, and blood products. T. Purgess 686:1-12. On February 28, 2002, Plaintiff's EKG read normal; therefore, there was no contra-indication for surgery. Jt. Ex. 2 at 256.

On or about March 7, 2002, Dr. Houten and Dr. Yamamoto met with Plaintiff to discuss the major and expected risks, and that the surgery might not work to relieve Plaintiff of his symptoms. T. Houten 574:20-575:19. Plaintiff testified that he was familiar with the operation and its risks, as he had been through the surgery three prior times, and wanted to have the surgery. T. Nemcik 183:21-184:16. Although Dr. Houten had heard of or read about reports of individuals where prolonged spine surgery led to post-operative vision loss, Dr. Houten did not inform Plaintiff of this risk because he considered it too remote. T. Houten 575:25-576:17.

Prior to the surgery, Plaintiff signed several consent forms. Plaintiff signed the official consent form for the surgery and anesthesia, which identified the participating surgeons, and acknowledged:

> The nature and purpose of the operation or procedure, possible alternative methods of treatment, the risks involved and the possibility of complications have been fully explained to me. I acknowledge that no guarantees have been made to me concerning the results of the operation or procedure. I understand the nature of the operation or procedure to be multilevel laminectomy and fusions hip grafts and pedicle screws.

Jt. Ex. 2 at 262. An impartial witness was present when the consent form was signed.

Plaintiff also signed a supplemental form, which verified that the physician spoke with Plaintiff about the procedure, the indications, risks, benefits, and alternative treatment options, and that Plaintiff had an opportunity to ask questions. Jt. Ex. 2 at 263. The form indicated that Plaintiff consented freely without fraud, duress, or coercion and that Plaintiff had decision-making capacity. *Id.* A separate consent form to allow blood transfusion, should that become necessary, was signed by Plaintiff. The form stated the risks associated with the transfusion of blood, even when all precautions are taken, and listed some of the known risks. Plaintiff's signature acknowledged that he read and understood the risks, alternatives, and expected results, had an opportunity to ask questions, and was aware that other unexpected risks or complications not discussed could arise and that no guarantees or promises were made regarding the transfusion. Jt. Ex. 2 at 264.

Despite the numerous disclosed risks, Plaintiff decided to proceed with the surgery. On March 20, 2002, Dr. Grush was assigned to head Plaintiff's anesthetic management during the spinal procedure. Dr. Grush reviewed Plaintiff's file, including his electronic medical chart, pre-operative evaluations, lab results, and imaging studies. Dr. Grush was aware that Plaintiff had prior surgeries and that two units of bank blood had been reserved for Plaintiff. Dr. Grush considered Plaintiff to be in acceptable medical condition for the surgery. T. Grush 692:13-694:11. Plaintiff was admitted into the VA Hospital during the evening of March 20, 2002, and received no food or drink past midnight.

B. March 21, 2002 Surgery

The morning of the surgery, the anesthesia team comprising of Dr. Grush and Mary Murphy, C.R.N.A. (collectively, the "anesthesia team") began caring for the patient at approximately 8:00 a.m. Dr. Grush conducted a pre-induction evaluation of Plaintiff, which included checking Plaintiff's vital signs, noting his height and weight, and confirming that Plaintiff received all necessary medications, signed the consent forms, and ingested nothing the night before. Jt. Ex. 2 at 324-35; 694:17-25. Dr. Grush also inspected Plaintiff's mouth to ensure that the opening was adequate to accept intubation. T. Grush 695:2-21.

Dr. Grush testified that he spoke with Plaintiff during this evaluation and asked Plaintiff why he was at the hospital to confirm that Plaintiff understood the nature of the procedure, and inquired whether Plaintiff had any questions. Dr. Grush then explained to Plaintiff that he was the anesthesiologist and would be inserting an intravenous and arterial line. T Grush 695:3-15. Further, he conveyed to Plaintiff that Plaintiff would be intubated, unconscious, and unable to move for the duration of the surgery, and that he would do his best to keep Plaintiff safe. *Id.* Dr. Grush admitted that he did not go into great detail explaining the risks associated with anesthesia to Plaintiff because he understood that the information had been conveyed to Plaintiff during his pre-operative evaluation. T. Grush 699:15-700:8. In his report, under "Planned Anesthetic Management," Dr. Grush indicated that anesthetic alternatives, procedural details, and relative risks and benefits were reviewed, all questions answered, and Plaintiff agreed to proceed. Jt. Ex. 2 at 325.

The anesthesia team was responsible for keeping Plaintiff stable during the surgery, monitoring and assessing his physiological status, and if any parameters went out of the normal range, to try and bring them back to normal. T. Purgess 629:13-22. The surgery room was

supplied with a variety of machines to help monitor Plaintiff's condition. Additionally, a perfusionist was on staff to operate the Cell Saver machine, which washed and recycled Plaintiff's shed blood. At approximately 8:10 a.m., while Plaintiff lay flat on his back, the anesthesia team administered general anesthesia to Plaintiff with an arterial line, which allowed for precise, repeated, and prompt laboratory analysis of the oxygen carrying capacity of Plaintiff's blood as well as the level of certain gasses in the blood. Jt. Ex. 2 at 325; T. Grush 697:4-5. Once Plaintiff was thoroughly anesthetized, an endotracheal tube was inserted and secured and his eyelids were taped shut. T. Grush 703:11-25.

Because Plaintiff had to be in the prone position in order to perform the surgery, he was placed on a frame referred to as a Wilson frame and his head was supported by a Mayfield rest. Jt. Ex. 3 at 11. The Wilson frame supports the bony prominences of a patient's body and has an adjustable central opening, which is specifically designed to allow the abdomen to hang freely. Dr. Houten adjusted the frame to accommodate Plaintiff's size. T. Grush 705:22-24. Once Plaintiff was placed on the Wilson frame in the prone position, Dr. Houten checked the positioning to ensure that no part of Plaintiff's body would be injured. T. Houten 580:5-23; T. Grush 706:23-707:9. Plaintiff's body was positioned flat and his head was in neutral position. T. Grush 706:13-22. A urinary catheter was also inserted. T. Grush, 707:1-3.

The surgeons began the actual spinal procedure at approximately 9:35 a.m. Jt. Ex. 2 at 291. Dr. Yamamoto assisted Dr. Houten. The surgery lasted approximately nine hours and there were no untoward events or complications. Jt. Ex. 3 at 5. During the procedure, the anesthesia team monitored Plaintiff's bodily functions with standard equipment and kept a handwritten chart that tracked the administration of medicine to Plaintiff, Plaintiff's heart rate, blood

pressure, respiration, oxygen intake, carbon dioxide output, ventilator settings, and fluid intake and output. Jt Ex.2 at 291-98.

Plaintiffs systolic and diastolic blood pressure was measured every five minutes. His systolic blood pressure dipped slightly after incision to 95 or 97; however, pressure was maintained between 100-120 throughout the procedure. Jt. Ex. 2 at 291. Deliberate hypotension was not used, T. Grush 707:11-22, and there were no episodes of severe or sustained hypotension.[2] The computer automatically recorded the mean arterial blood pressures ("MAP") and posted the readings on the computer monitor in real time for the anesthesia team to read. None of the doctors who attended to Plaintiff on the day of the surgery, or while he was in recovery, found that Plaintiff was significantly hypotensive. Concern would have been raised only if Plaintiff's systolic pressure dropped to 90 for a sustained period of time. T. Houten 587:10-22.

Furthermore, intra-operative hypotension has not been scientifically established to be a causative factor for PION and it was not a factor here. Plaintiff had been turned prone around 9:15 or 9:30 a.m. The lowest systolic pressure readings occurred right before and after the initial incision was made to Plaintiff at 9:35 a.m. Jt. Ex. 2 at 291. Therefore, the time period Plaintiff's blood pressure was at its lowest was not long enough to be considered part of the multi-factorial causation elements that can lead to PION.

Plaintiff's MAP was 80. T. Roth 354. During the surgery, Plaintiff's MAP ranged between 70 and 90. No standard of care in 2002 required the anesthesiologists to maintain Plaintiff's blood pressure at a higher level than what was recorded in his clinical record

[2] Hypotension occurs when the blood pressure is abnormally low.

anesthesia. Raising the pressure to an artificially higher level was possible, however, each action the doctors could take to raise the level involved various risks to Plaintiff and his health. Autoregulation of Plaintiff's blood pressure was not necessary because his pressure did not swing between extreme highs or lows.

The anesthesia team sent arterial line blood samples to the laboratory for analysis throughout the surgery. Jt. Ex. 2 at 119-22. The results can be summarized as follows:

Date	Time	Hematocrit (HCT)
March 21, 2002	8:32 a.m	40
March 21, 2002	10:43 a.m.	40
March 21, 2002	11:50 a.m.	44
March 21, 2002	12:57 p.m.	42
March 21, 2002	13:51 p.m.	39
March 21, 2002	15:35 p.m.	41
March 21, 2002	18:23 p.m.	37

Plaintiff's hematocrit level was well-maintained between 37 and 40. According to the ASA Guideline on Blood Replacement, anemia is indicated by a hematocrit of 30 HCT or less. T. Purgess 651:18-652:10. Because there was no sign of anemia, the doctors did not transfuse Plaintiff.

Throughout the surgery, blood is salvaged from the operative site, cleaned through a Cell Saver machine, and returned to the patient intravenously in concentrated form. Dr. Grush began reinfusing Plaintiff with his Cell Saver blood at about 3:10 to 3:30 p.m. T. Grush 716:23-718:20. Dr. Grush testified that he did not want to give Plaintiff the Cell Saver blood too early on because Plaintiff would bleed it right back out, and each time blood is suctioned into the Cell Saver

machine, the potassium content gets damaged. *Id.* The anesthesia team replaced part of Plaintiff's blood loss with 1,250 ml of Cell Saver blood. Jt. Ex. 2 at 297. Plaintiff's total blood loss was estimated at 2,000 ml. *Id.*

At the time of Plaintiff's surgery, there was no specific guideline regarding blood transfusion at a particular HgB/HCT reading. On the contrary, ASA Practice Guidelines called for blood replacement "as necessary" and that transfusion with banked blood was rarely indicated if the hemoglobin concentration level was greater than 10 (approximately 30 HCT). T. Frost 149:6-150:6, 153:14-19. There is no evidence that an earlier transfusion of the Cell Saver blood would have prevented Plaintiff's vision loss.

In addition to losing blood, Plaintiff lost large amounts of other fluids during the surgery. These fluid losses are the result of an open wound and evaporation. Because Plaintiff was restricted from eating and drinking for many hours prior to the surgery and the anesthetic drugs used on Plaintiff caused the blood vessels to dilate, a need for more fluid to fill the vessels. Dr. Roth, the Government's neuro-anesthesiologist expert, estimated Plaintiff's fluid maintenance requirement to be 3,000 ml. Dr. Roth calculated that Plaintiff lost between 5.2 and 10.7 liters of fluid and, thus, approximated that between 8.2 and 13 liters of fluid had to be replaced. T. Roth 395:6-396:19. Therefore, fluid replacement was necessary in order to maintain blood volume and pressure.

Fluid replacement is a matter of the anesthesiologist's judgment and is based on a variety of factors in the operating room. T. Roth 391:20-392:10. The scientific literature published prior to March 2002 does not establish what the appropriate level of fluid replacement was for a

prolonged spine surgery. A total of 9,000 ml of crystalloid solution[3] was administered, T. Grush 714:18-715:13, which means that, when combined with the 1,250 ml of Cell Saver blood, a total of 10.25 liters of fluid was replaced. This amount did not exceed the amount of fluid Plaintiff lost. T. Grush 396:8-19. Plaintiff did not become overloaded with fluid. He showed no signs of pulmonary edema or decreased arterial oxygen concentration, and the ventilator settings did not need to be turned higher. T. Roth 400:16-401:5. Further, Plaintiff's tissue did not become "boggy" or seep the fluid when the retractors closed in on it. T. Houten 583:7-18. Dr. Frost testified that overhydration must have led to edema in all dependent tissue, particularly around the eyes and abdomen, and that the edema led to increased intra-ocular and -abdominal pressures, which reduced the oxygen perfusion to the posterior optic nerve. T. Frost 107-09. Dr. Frost, however, failed to cite any study to support her theory.

It is unclear what Plaintiff's total urine output was; while the records indicate 330 ml, if the outputs are totaled, the sum only equals 230 ml. Jt. Ex. 2 at 297. At either output, Plaintiff's level would be considered low. Surgery patients in the prone position can have low urine output for unexplained reasons. T. Purgess 657:4-19. Additionally, if a patient is under anesthetic, a patient's anti-diuretic hormones could stop the outflow of urine. T. Purgess 654:20-655:2. Urine output, however, is one of a number of parameters anesthesiologists monitor throughout a surgery. While Plaintiff's urine output was low and Drs. Grush and Purgess expressed concern

[3] The VA anesthesiologists were aware of the debate about whether colloid solution should be added to the crystalloid solution for fluid replacement, and there was no requirement by the ASA for anesthesiologists to use colloid. T. Roth 397:16-400:15. Colloid contains larger molecules of protein, however, it can interfere with blood clotting and transmit viruses. Crystalloid is easier to infuse while colloid remains in the vasculature longer. *Id.* While Dr. Frost posited that if colloid had been used, there would have been less edema, she conceded that using colloid has not been shown to prevent PION. T. Frost 163.

about the level, there was no cause for alarm because Plaintiff's other parameters appeared acceptable. T. Grush 720;17-721:21. Furthermore, Plaintiff's low urine output was not caused by abdominal compartment syndrome. The operative report did not record any indication of the condition. Jt. Ex. 3 at 2-5. There was no damage to Plaintiff's internal abdominal organs and the venitlator readings remained normal, which demonstrates that Plaintiff had no problem breathing. T. Purgess 655:3-656:10; Jt. Ex. 2 at 291-98.

Dr. Purgess relieved Dr. Grush in the operating room around 4:30 p.m. T. Purgess 636:18-24. He assisted Dr. Grush with various tasks such as reviewing the blood pressures, looking at the urine output and fluid input, and assessing Plaintiff and the intravenous lines until Dr. Grush left around 6:15 p.m. T. Purgess 636:25-638:18; T. Grush 723:20-22. Dr. Purgess testified that Plaintiff was not overloaded with fluid and did not evidence any signs of abdominal compression. T. Purgess 655:9-15. Dr. Purgess did express some concern about Plaintiff's low urine output and noted that when Plaintiff was turned onto his back in the operating room, his urine output increased. T. Purgess 654:20-655:8; 657:4-19.[4]

C. Post-Surgery Recovery

After surgery, Plaintiff recovered in the SICU. Plaintiff was sedated and intubated. T. Purgess 658:24-659:23. Dr. Yamamoto checked on Plaintiff during the evening on March 21, 2002, and recorded that he was in stable condition. Jt. Ex. 2 at 326. By 8:00 p.m. that night, Plaintiff's urine output had increased to 100 ml per hour and by 9:00 p.m., he had excreated

[4] The Court refrains from discussing intra-ocular pressure, glucose levels and base excess levels as the Court finds that they cannot be considered part of the multi-factorial causative elements of Plaintiff's PION.

another 90 ml, followed by another 140 ml the next hour. Jt. Ex. 2 at 1057. Plaintiff's lab results and blood samples demonstrated that he was not in kidney failure. T. Grush 725:1-726:5. At 10:44 p.m., a respiratory therapist reported that Plaintiff's arterial blood gasses were good. Deft. Ex. 2 at 327. About an hour later, a nurse recorded that Plaintiff's lungs were clear to auscultation. *Id.* at 328.

Plaintiff's sedation was discontinued at 7:00 a.m. on March 22, 2002, and Plaintiff was taken off the respirator at 7:15 a.m. Jt. Ex. 2 at 334. Plaintiff's vital signs were stable and his systolic blood pressure was greater than 160. Jt. Ex. 2 at 1073. Around 9:00 a.m., Plaintiff awoke and complained to the nurse that he could not see. Jt. Ex. 2 at 1075 and 1093 n.33. Dr. Yamamoto notified Dr. Houten, who came to examine Plaintiff. Dr. Houten observed diminished vision and peri-orbital edema. Dr. Houten ordered an MRI of the brain and called for an emergency ophthalmology consult. Jt. Ex. 2 at 338. The MRI showed no evidence of infarction. Jt. Ex. 2 at 1231.

Dr. Richard Levy, a neuro-ophthalmology resident, dilated and examined Plaintiff's eyes at 1:00 p.m. Jt. Ex. 2 340-41. Plaintiff's pupils did not react equally to light and Dr. Levy reported that there might be some intra-ocular pressure. *Id.* The optic disc appeared sharp, pink, and flat, which indicated no swelling or pallor, but Plaintiff's eyelids were moderately swollen although they moved well. *Id.* Based on Plaintiff's systolic blood pressure being maintained at 100-120 during and after the surgery, Dr. Warren did not consider Plaintiff to have been hypotensive during the procedure. T. Warren 314:9-315:20. Additionally, Dr. Houten reviewed Plaintiff's chart and found nothing that could explain Plaintiff's vision loss. T. Houten 581:10-21. Dr. Levy discussed Plaintiff's case with Dr. Warren and they diagnosed Plaintiff with PION.

Jt. Ex. 2 at 340.

Ischemic optic neuropathy ("ION") is a sudden, painless vision loss that can occur in both a non-surgical or post-operative setting. T. Warren 313:20-314:1. PION affects the portion of the optic nerve that is closer to the brain, away from the eyeball, and occurs less frequently than anterior ischemic optic neuropathy ("AION"). PION stems from a different etiology than AION and the risk factors for the two conditions differ. Dr. Frohman explained that in diagnosing vision loss, an ophthalmologist examines the optic disc through an ophthalmoscope, and looks at the optic disc, which is the anterior optic nerve head. If the doctor examines the patient soon after the sight loss and sees a white swelling of the optic nerve, the diagnosis is AION. If, however, the patient does not have vision, but the optic disc appears normal, then the problem lies in an area the doctor cannot see, the posterior optic nerve, and, therefore, it is PION. T. Frohman 804:3-805:1.

Subsequently, Plaintiff's vision in his left eye has improved; however, follow-up eye examinations showed that vision did not return to Plaintiff's right eye. Plaintiff has retained the ability to read, perform activities of daily living, and occasionally drive a car.

D. Understanding of PION in 2002

What an anesthesiologist should have known about PION in 2002 can be evidenced by what was written in the medical literature at the time. Medical literature provides doctors with scientific proof that a trait, event, or treatment is a causative factor leading to a particular result. Journal articles generally provide the current developments in the specific field of medicine, and range from scientific studies to literature reviews to individual case studies. The two leading

journals for anesthesiologists include *Anesthesiology* and *Anesthesia & Analgesia*. T. Frost 57:24-58:7; T. Roth 351:6-11.

In researching post-operative vision loss after spine surgery, the best evidence of its occurrences and its causes comes from a combination of an analysis of the literature and consultants' opinions. It is necessary, at times, for doctors to base their practice on speculation rather than reliable scientific method. T. Frost 135:23-136:5. Between 1968 and 2002, sixteen cases of PION following spine surgery had been reported in all of the relevant medical literature. T. Roth 565:4-14. Before Plaintiff's surgery, only seven articles identified cases of PION after spine surgery. A survey of the medical literature at the time indicates that PION was extremely rare, with an incidence rate between .03 and .1%. T. Roth 348:22-25. A causative factor appeared to be prolonged spine surgery; however, causation can be considered multi-factorial as a combination of a variety of risk factors appears to lead to PION rather than one specific factor.

Although awareness of post-operative vision loss was growing, many anesthesiologists were unaware of its occurrence. Drs. Purgess and Grush read *Anesthesiology* and *Anesthesia & Analgesia*. T. Purgess 622:8-11; T. Grush 692:5-12. Both doctors had knowledge of incidents of post-operative vision loss in spine surgeries; however, they understood this to be a rare occurrence. T. Purgess 684:12-23; T. Grush 699:9-12 and 724:15-23. Moreover, it was not the standard of care in 2002 to tell prospective spine surgery patients about post-operative vision loss. *Id.*

E. Pre-Operative Consult and Pre-Induction Evaluation

The purpose of a pre-operative consult is to evaluate whether the patient can undergo the

proposed surgery. The participating doctors have not yet been identified and because the final diagnosis or extent of the surgery might not yet have been proposed, the patient has not consented to any medical procedure. The pre-induction evaluation, on the other hand, is conducted by the anesthesiologist assigned to the surgery on the day of the surgery, and the treating surgeon is also available for any discussion or questions. The management of anesthesia gets planned at this stage and not before.

An anesthesiologist is only required to advise the patient of the risks associated with the anesthesia management, which Dr. Frost conceded in her testimony. T. Frost 148:15-18. There is no duty to disclose the risks of the surgery itself. The pre-operative anesthetic consultation required the anesthesiologists to review Plaintiff's file and medical history in order to identify any health issues that could affect the anesthetic. T. Roth 338:20-339:10. The evaluation is conducted to ensure that the patient is in the best shape he can be, from a medicine point of view, prior to undergoing the anesthesia and surgery. *Id.*

Dr. Grush performed the pre-induction evaluation of Plaintiff on the day of Plaintiff's surgery. As the anesthesiologist conducting this evaluation, Dr. Grush should have reviewed the medical history, diagnosis, medications, and allergies. Further, he should have assessed the anesthesia plan, talked to Plaintiff about the plan, and physically examined Plaintiff's airway. Lastly, Dr, Grush should have verified Plaintiff's consent to the anesthesiology plan. T. Frost 52:15-53:17 (explaining the pre-induction evaluation as the pre-anesthetic assessment). Dr. Grush performed all of these tasks.

III. Conclusions of Law

A. Standard of Review

Under the Federal Tort Claims Act, 28 U.S.C. 2764, the United States will be liable:

> "...for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."

28 U.S.C. 1346(b)(1). To recover under the Federal Tort Claims Act, Plaintiff must prove negligence. *See Laird v. Nelms*, 406 U.S. 797, 799 (1971) ("the Federal Tort Claims Act itself precludes the imposition of liability if there has been no negligence or other form of 'misfeasance or nonfeasance,' on the part of the Government") (internal quotations omitted). Here, because Plaintiff's surgery took place in New York, the laws of that state will apply.

B. Analysis

i. Standard of Care

To establish a claim for medical malpractice under New York law, "a plaintiff must prove (1) that the defendant breached the standard of care in the community, and (2) that the breach proximately caused the plaintiff's injuries." *Arkin v. Gittleson*, 32 F.3d 658, 664 (2d Cir. 1994). To prevail, Plaintiff "must show by a preponderance of the evidence that the treating physicians breached their duty of care to [him], they cause his injuries." *Metzen v. United States*, 19 F.3d 795, 807 (2d Cir. 1994). A physician owes his patient "(1) a duty to possess the requisite knowledge and skill such as is possessed by the average member of the medical profession; (2) a duty to exercise ordinary and reasonable care in the application of such professional knowledge

and skill; and (3) the duty to use his best judgment in the application of this knowledge and skill." *Hale v. State*, 53 A.D.2d 1025, 1025 (N.Y. Sup. Ct., App. Div. 1976). Further, in proving his case, Plaintiff must present expert medical opinion. "Except to matters within the ordinary experience and knowledge of lawmen, in a medical malpractice action, expert medical opinion evidence is required to demonstrate merit." *Fiore v. Galang*, 64 N.Y.2d 999, 1001 (N.Y. 1985).

Plaintiff has not demonstrated that the anesthesiologists breached the standard of care in 2002. At all times during Plaintiff's procedure, the anesthesiologists acted within the standard of care. No standard of care protocols existed in March 2002, regarding the pre-operative consult or pre-induction evaluation, fluid and blood replacement, intra-operative blood pressure monitoring, or urine output, from which the doctors deviated. Differences of opinion existed as to the type of fluid that should be used when replacing fluid loss during surgery. Some physicians opted using crystalloid for fluid replacement; others used colloid. Drs. Grush and Purgess were aware of the two options and, using their professional judgment, determined that using the crystalloid fluid, alone, was the best solution. Additionally, the standard of care did not demand that the physicians transfuse Plaintiff. Plaintiff's hematocrit level, while low at times, did not necessitate a transfusion nor did it impact when the physicians should have given Plaintiff the Cell Saver blood. No level of hematocrit has ever been determined to be preventive of PION and Plaintiff failed to establish that a transfusion rather than Cell Saver blood, or an earlier administration of Cell Saver blood, would have prevented Plaintiff's PION. Furthermore, Plaintiff never became hypotensive during the procedure and, therefore, the physicians did not violate any standard of care by failing to take measures to increase his blood pressure.

Moreover, the Court finds that proximate cause is lacking. None of the alleged standard

of care breaches caused Plaintiff's PION. Fluid overloading, resulting in edema around the eyes, in the lungs, and in the abdomen, has never been established as a risk factor for PION, and the level and duration of hypotension that would be required during surgery to cause PION remains unknown and undefined. The medical community has not yet established what mechanism causes PION. At best, physicians have concluded that the causes are multi-factorial. In other words, there is no way to predict which patients are more susceptible to PION and, as such, no protocol to prevent PION has been developed. Dr. Frost, herself, even testified that there is no single factor that causes PION; rather, it is several factors together that can lead to the condition. T. Frost 164:7-16. Dr. Frost could not state with a reasonable degree of certainty that adding colloid to the crystalloid, maintaining a higher blood pressure, transfusing earlier, increasing venous pressure, or giving insulin or vasopressors would have prevented Plaintiff's PION. T. Frost 172:3-19. At best, causation is multi-factorial.

Plaintiff has failed to show that Defendant deviated from the standard of care. Furthermore, Plaintiff has failed to establish any causal connection between the actions taken by the anesthesiologists and Plaintiff's post-operative diagnosis of PION. Therefore, the Court enters judgment in favor of Defendant on Plaintiff's claim of negligence.

ii. Informed Consent

New York Public Health Law § 2805-d provides:

> 1. Lack of informed consent means the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical...practitioner would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation.

> ...
> 3. For a cause of action therefore it must also be established that a reasonably prudent person in the patient's position would not have undergone the treatment or diagnosis if he had been fully informed and that the lack of informed consent is a proximate cause of the injury or condition for which recovery is sought.

See also Johnson v. Columbia Univ., 99 Civ. 3415, 2003 U.S. Dist. LEXIS 20932, at *57-58 (S.D.N.Y. Nov. 19, 2003) (noting that the doctrine of informed consent has been codified in § 2805-d of the New York Public Health Law and stating the necessary elements to establish a cause of action for medical malpractice based lack of informed consent).

A physician's failure to advise a patient of the remote possibility of a risk that is extremely uncommon or an unexpected complication of surgery does not constitute a deviation from the standard of care. *See McElroy v. Yousuf*, 268 A.D.2d 733, 736 (N.Y. App. Div. 2000) (recognizing that while a physician "is required to inform his patient of all reasonably foreseeable risks relative to a certain medical procedure," where the risk is "extremely uncommon and an unexpected complication...failure to of [the doctor] to specifically advise [a patient] of this remote possibility did not constitute a departure from the required standard of care"); *see also Blackmon v. Strong Mem'l Hosp.*, 289 A.D.2d 1018, 1018 (N.Y. App. Div. 2001) ("Failure to advise patients of remote risks does not constitute a departure from the required standard of care.").

i. Disclosure of Reasonably Foreseeable Risks

Based upon the journal articles, as well as the expert testimony, the Court finds that the low incidence of post-operative vision loss in spine surgery was not a reasonably foreseeable risk such that the physicians had a duty to disclose it to Plaintiff. The literature in the anesthesiology

journals found that post-operative vision loss was a rare and unpredictable result of spine surgery. Furthermore, even if PION was a reasonably foreseeable risk in 2002, the duty of informing Plaintiff of the risks associated with the spine surgery he underwent does not fall on the anesthesiologists.

The burden of obtaining a patient's informed consent is on the physician who prescribed or performed the procedure. *See Nisenholtz v. Mt. Sinai Hosp.*, 126 Misc. 2d 658, 663 (N.Y. Sup. Ct. 1984) ("it is clearly not necessary that every physician or health care provider who becomes involved with a patient obtain informed consent to every medical procedure to which the patient submits. Rather, it is the responsibility of a physician to obtain informed consent to those procedures and treatments which the physician actually prescribes or performs"). Moreover, "while a participant may be responsible to the patient to explain the particular risks of his phase of the treatment, for example, surgery or anesthesia, it does not automatically follow that he has an obligation to inform the patient of the risks of another participant's treatment." *Prooth v. Wallsh*, 105 Misc. 2d 603, 605 (N.Y. Sup. Ct. 1980).

The Court finds that while the anesthesiologists who attended to Plaintiff were responsible for advising Plaintiff about the risks associated with the anesthetic agents and procedures they would be using throughout the course of the surgery, they were not responsible for informing Plaintiff about the risks associated with the surgery itself, such as PION. Moreover, the standard of care for anesthesiologists in 2002 did not mandate that they inform their patients that post-operative vision loss was a risk of spine surgery. Anesthesiologists are generalists in their field and cannot be expected to have knowledge of the risks of each and every kind of surgery. Even Dr. Frost testified that while it would be prudent to tell a patient of the

risk, there was no ASA standard that an anesthesiologist must disclose the risk. T. Frost 175:9-176:17. Furthermore, the risk factors for PION, such as a lengthy spine surgery in the prone position, are not in the control of the anesthesiologists. T. Frost 124:6-8.

ii. Proximate Cause

"In an action raising lack of informed consent, there are two separate causation elements: the 'but for' and the proximate cause elements...this 'but for' relation is established when the [fact finder] concludes that a reasonably prudent person in the patient's position would not, if fully informed, have consented to the treatment." *Flores v. Flushing Hosp. & Med. Ctr.*, 109 A.D.2d 198, 200 (N.Y. App. Div. 1985). *See also Barbato v. Livingston*, 2008 NY Slip Op 50188U, at *5 (N.Y. Sup. Ct. 2008) ("a plaintiff must also establish that the treatment would not have occurred 'but for' the doctor's failure to properly inform her. That is, 'that a reasonably prudent person in the patient's position would not, if fully informed, have consented to the treatment.'") (internal citations omitted). The lack of informed consent must be the proximate cause of Plaintiff's injury.

The Court has determined that a reasonably prudent patient in the same position as Plaintiff would have undergone the procedure had he been fully informed. Despite his prior spine surgeries, physical therapy, and pain management, Plaintiff continued to suffer from spinal deterioration, which was affecting his quality of life. A reasonably prudent patient in Plaintiff's position would still have undergone the spine surgery regardless of the rare risk - .03 to .1% - of post-operative vision loss. Plaintiff had undergone three previous spine surgeries, all under general anesthesia, without any complications. Additionally, the anesthesiologists attending to

Plaintiff had never encountered cases of post-operative vision loss in any of their other patients. The anesthesiologists disclosed all of the relevant information surrounding the procedure and the Court finds that a reasonably prudent patient in as much pain as Plaintiff, and with the same knowledge as Plaintiff, would have undergone the surgery. Like Plaintiff, a reasonably prudent patient would want spine surgery if it would alleviate the pain he experienced and allowed him to remain ambulatory and functioning.

Moreover, Plaintiff himself testified that had he been told of the risk of post-operative vision loss or PION that he would only have "hesitated" about having the surgery. T. Nemcik 220:13-23. Hesitating is not the same as not going through with the surgery. Plaintiff wanted the surgery and intended to have it despite the risk of death or paralysis. T. Nemcik 209:8-25. Plaintiff also knew that other risks included heart failure and in the event of a transfusion, he risked contracting AIDS, malaria, and hepatitis. T. Nemcik 183:18-184:23. Plaintiff had faith in the doctors based on his other surgeries. T. Nemcik 209:13-17. The Court, therefore, finds that Plaintiff has failed to prove by a preponderance of the evidence that, but for the anesthesiologists' failure to tell him about post-operative vision loss, he would not have undergone the surgery.

IV. Conclusion

For the reasons stated above, it is therefore the finding of the Court that Defendant was not negligent in its care of Plaintiff. Plaintiff failed to establish by a preponderance of evidence that Defendant's actions constituted medical malpractice or a violation of informed consent. Therefore, the Court enters judgment on behalf of Defendant. An appropriate order follows.

/s/ JOEL A. PISANO
United States District Judge

Dated: July 7, 2008